

### **REMARKS**

This paper is provided in response to the Office Action mailed February 4, 2008. Claims 1-10 are currently pending. Claim 1 is amended to remove the double bond objected to by the examiner. This amendment is supported throughout the specification. No new matter is added. Reconsideration and allowance are requested for the following reasons:

#### **Rejection under 35 U.S.C. § 112**

Claims 1 and 3 were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Applicants respectfully traverse the rejection. Without acquiescing in the rejection, Applicants submit that the treatment of the conditions in the claims: bruises, vascular disorder on the skin, spider veins, varicoses, blotches on the face, purpura on the face body or legs, irritation following use of chemical peel, and Schamberg's disease, are related because treatment of all of the conditions requires the disappearance of extravascular blood. For example, Schamberg's disease is a progressive purpuric dermatitis. Patients who develop this disease have leaky blood vessels. Treatment for the disease would require the disappearance of extravascular blood.

Since the specification in the instant application shows that Vitamin K1 oxide is suitable for the treatment of bruises, and since bruises are linked to other conditions in the claims, Applicants have sufficiently enabled the claims. Withdrawal of the rejection is respectfully requested.

#### **Rejection under 35 U.S.C. § 103**

Claims 1 and 3-10 were rejected under 35 U.S.C. § 103(a) as unpatentable over Elson (U.S. Patent 5,510,391) in view of Ryall et al. (J. Med. Chem. 1990 (33), 1790-1797). Applicants respectfully traverse the rejection.

The examiner states that Elson teaches that synthetic Vitamin K analogs can be used in cosmetic and/or pharmaceutical formulation for use in treating the skin and that Vitamin K1

oxide would be considered to be a species of the generic teaching of Elson. Applicants disagree. Claim 1 as amended recites a method for the treatment of dermatological lesions by submitting a lesion to a composition comprising the compound of formula I in a pharmaceutical or cosmetic carrier. Claims 3-10 depend from claim 1 and incorporate all the limitation thereof. Elson teaches the use of vitamin K1 in a cream formulation, wherein the formulation also contains ethyl alcohol and lecithin. However, as conceded in the office action, Elson does not teach the use of a formulation comprising a compound of the specific formula shown in the present claims (i.e. Vitamin K oxide). Instead, the examiner contends that Elson suggests the equivalency of all vitamin K1 analogs and pharmaceutical formulations used for skin treatment. Applicants disagree with this contention and submit that the vitamin K1 oxide of the present claims is not encompassed by the vitamin K analogs taught in Elson. In fact, the reference specifically indicates that the analogs of vitamin K are limited to the known synthetic analogs which currently include vitamins K3, K4, K5, K6 and K7. (Elson '391, at col. 1, ll. 37-39). There is no teaching or suggestion in Elson that vitamin K1 oxide was considered an analog of vitamin K.

Given the difference between vitamin K1 oxide and vitamin K1, a person of ordinary skill in the art would not consider a vitamin K1 formulation an analog of a vitamin K1 oxide formulation. In addition to structural differences, vitamin K1 oxide is not metabolized or broken down by exposure to light, and therefore, formulations of vitamin K1 oxide would have different skin treatment properties than formulations of vitamin K1 in native form. Therefore, Elson does not teach a composition comprising vitamin K1 oxide, and therefore, all the limitations of the present claims are not disclosed and no prima facie case of obviousness has been made.

The Examiner states that Ryall et. al. teaches Vitamin K1 epoxide analogs, including a homolog to that of Applicant's. Examiner further states that varying Ryall et. al.'s compounds by one homologous isoprene unit, would give rise to the compound of Applicants' claims, therefore making Applicant's method claims obvious. Applicant respectfully disagrees.

Prior art which does not provide any utility for the disclosed compounds is insufficient to establish obviousness. *Ortho McNeil Pharm., Inc. v. Mylan Labs., Inc.*, Nos. Civ A. 04-1689, 2006 WL 1517749, at \*6 (D.N.J. May 30, 2006) ("Where the prior art reference neither discloses

nor suggests a utility for certain described compounds, why should it be said that a reference makes obvious to one of ordinary skill in the art an isomer, homolog or analog of related structure, when that mythical, but intensely practical, person known of no practical reason to make the reference compounds, much less any structurally related compounds?" (quoting *In re Stemniski*, 444 F.2d 581, 586 (C.C.P.A. 1971)). Ryall et al. does not provide for any utility for the disclosed vitamin K1 epoxides. As a result, there would no reason that for one of ordinary skill in the art to select the compounds disclosed in Ryall et al. for a method of treating dermatological lesions. Furthermore, applicants submit that the Ryall et al. reference does no remedy the deficiency of the Elson reference.

As the references cited by the Examiner do not disclose the claim limitations, no prima facie case of obviousness has been made, and withdrawal of the rejection is respectfully requested.

### Conclusion

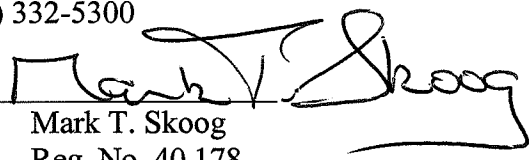
In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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